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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,382	10/03/2001	Su-Chun Zhang	960296.98211	9657
27114	7590	06/02/2004	EXAMINER	
QUARLES & BRADY LLP 411 E. WISCONSIN AVENUE, SUITE 2040 MILWAUKEE, WI 53202-4497			NGUYEN, QUANG	
			ART UNIT	PAPER NUMBER

1636

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/970,382

Applicant(s)

ZHANG ET AL.

Examiner

Quang Nguyen, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,11-13,18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 is/are allowed.
- 6) ☒ Claim(s) 1,3-9,11-13 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicants' amendment filed on 3/22/04 has been entered.

Amended claims 1, 3-9, 11-13 and 18-19 are pending in the present application, and they are examined on the merits herein.

Claim Objections

Claim 13 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. This is because in claim 1 from which claim 13 is dependent, the culture medium in step (c) lacks other proliferation/differentiation agents and yet insulin (a proliferating agent for certain cells) is recited in the culture medium of the method of claim 13.

Response to Amendment

The rejection of claim 13 under 35 USC 112, First paragraph, is withdrawn in light of Applicants' amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Amended claims 1, 3-9, 11-13 and 19 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

A method of differentiating primate embryonic stem cells into neural precursor cells, comprising the steps of:

- (a) obtaining a primate embryonic stem cell culture,
- (b) propagating the stem cells, wherein embryoid bodies are formed, and
- (c) culturing the embryoid bodies in a medium consisting essentially of

DMEM/F12, insulin, transferrin, progesterone, putrescine, sodium selenite, heparin and an effective amount of fibroblast growth factor 2, wherein neural precursor cells are generated and wherein neural precursor cells form rosette formations,

does not reasonably provide enablement for a method of differentiating primate embryonic stem cells into neural precursor cells as claimed wherein the embryoid bodies are simply cultured in a medium containing an effective amount of fibroblast growth factor 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for the same reasons already set forth in the previous Office Action mailed on 1/2/04 (pages 2-5).

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Response to Arguments

Applicants' arguments related to the above rejections in the Amendment filed on 3/22/04 (pages 6-9) have been fully considered, but they are not found persuasive.

With respect to claim 19, Applicants argue that the recited medium comprises the different elements suggested by the Examiner with an additional element "in the absence of other proliferation/differentiation agents", and therefore the claim should be allowable. With respect to amended claim 1, Applicants assert that the cell culture aspects of the media are known to one of skill in the art.

Please note that Applicants' culture conditions result in a unique product (the generation of neural precursor cells from primate embryonic stem cells in a culture, and wherein the neural precursor cells form rosette formations), and the chemically defined medium used by Applicants (DMEM/F12, insulin, transferrin, progesterone, putrescine, sodium selenite, heparin and an effective amount of fibroblast growth factor 2) is an essential factor for the generation of such a unique product. This is the subject matter of new claim 18, which is deemed to be allowable. In contrast, the medium in step (c) of the amended claim 1 or in step (c) of new claim 19 is not necessarily limited to the chemically defined medium disclosed and taught by Applicants to obtain the unique product. Furthermore, at the filing date of the present application, although various groups reported the preparation of neural progenitor cells by culturing stem cell populations, including primate embryonic stem cells, in a medium comprising or containing bFGF or fibroblast growth factor 2, none of the groups has generated neural precursor cells that form rosettes (See Carpenter, M.K., WO 01/88104; IDS; Lee et al.,

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WO 01/83715; IDS; Reubinoﬀ et al., 2002/0068045 A1; IDS). This indicates that the presence of ﬁbroblast growth factor 2 in a culture medium is not suﬃcient for the diﬀerentiating primate embryonic stem cells into neural precursor cells that form rosette formations, and that the chemically deﬁned medium plays an important role in determining the attainment of the desired product.

Accordingly, amended claims 1, 3-9, 11-13 and 19 stand rejected under 35 U.S.C. 112, ﬁrst paragraph, for the reasons already set forth in the previous oﬃce action mailed on 1/2/04.

Conclusion

Claim 18 is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this ﬁnal action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a ﬁrst reply is ﬁled within **TWO MONTHS** of the mailing date of this ﬁnal action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this ﬁnal action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (703) 872-9306.

Quang Nguyen, Ph.D.


DAVID GUZO
PRIMARY EXAMINER